



California Device Recall Information Sheet

Megadyne Recalls Mega Soft Reusable Patient Return Electrode

Recall Date	Product Description	Recalling Firm	Recall Reason
7/10/2024	Megadyne" Mega Soft" Reusable Patient Return Electrode Model/Catalog Number: 0835 Software Version: N/A Product Description: Reusable Patient Return Electrode, Mega Soft, Dual Cord, Adult, For Patients Weighing over 25lbs. (11.4kg), 117cm Long x 51cm Wide x 1.25cm Thick Component: No	MEGADYNE MEDICAL PRODUCTS, INC. Blue Ash, Ohio	To limit the use of the Mega Soft Pads to patients aged 12 or older to mitigate the potential risk of pat- ient burns identified with use of Mega Soft pads.
7/10/2024	Megadyne" Mega Soft" Reusable Patient Return Electrode Model/Catalog Number: 0830 Software Version: N/A Product Description: Reusable Patient Return Electrode, Mega Soft, Single Cord, Adult, For Patients Weighing over 25lbs (11.4Kg), 117cm Long x 51cm Wide x 1.25cm Thick Component: No	MEGADYNE MEDICAL PRODUCTS, INC. Blue Ash, Ohio	To limit the use of the Mega Soft Pads to patients aged 12 or older to mitigate the potential risk of pat- ient burns identified with use of Mega Soft pads.
7/10/2024	MEGADYNE" MEGA 2000" Patient Return Electrode Patient Return Electrode Model/Catalog Number: 0800 Software Version: N/A Product Description: Reusable Patient Return Electrode, Mega 2000, Adult, For Patients Weighing over 25lbs. (11.4Kg), 91cm Long x 51cm Wide Component: No	MEGADYNE MEDICAL PRODUCTS, INC. Blue Ash, Ohio	To limit the use of the Mega Soft Pads to patients aged 12 or older to mitigate the potential risk of pat- ient burns identified with use of Mega Soft pads.

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Megadyne" Mega Soft" Reusable Patient Return Electrode Product Code: 0835; UDI-DI: 10614559101872; Lot Number: All distributed lot numbers. Product code has been discontinued from future production.</p>	1463 Units Nationwide	July 2024 and prior
I	<p>Megadyne" Mega Soft" Reusable Patient Return Electrode Product Code: 0830; UDI-DI: 10614559101797; Lot Number: All distributed lot numbers. Product code has been discontinued from future production.</p>	2584 Units Nationwide	July 2024 and prior
I	<p>Megadyne" Mega Soft" Reusable Patient Return Electrode Product Code: 0800; UDI-DI: 10614559100936; Lot Number: All distributed lot numbers. Product code has been discontinued from future production.</p>	259 Units Nationwide	July 2024 and prior

For additional information, please visit the [FDA website 0835](#), [0830](#) and [0800](#).

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